

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| UNITED STATES OF AMERICA |) | |
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| |) | |
| v. |) | Criminal No. 05-10102-JLT |
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| JOHN BRUENS, MARY STEWART, MARC |) | |
| SIROCKMAN, MELISSA VAUGHN |) | |
| |) | |
| Defendants. |) | |
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UNITED STATES' OPPOSITION TO DEFENDANTS'
MOTION TO STRIKE SURPLUSAGE IN THE INDICTMENT

The United States of America, by its attorney, Michael J. Sullivan, United States Attorney for the District of Massachusetts, opposes the motion of the defendants to strike surplusage in the indictment. The United States submits this memorandum in support of its opposition.

STATEMENT OF THE CASE

1. Introduction

On April 14, 2005, an eight-count indictment was returned against the defendants, John Bruens ("Bruens"), Mary Stewart ("Stewart"), Melissa Vaughn ("Vaughn"), and Marc Sirockman (Sirockman), (collectively "the defendants"). Count One of the Indictment charged the defendants with conspiracy to offer and pay illegal remunerations to physicians, in violation of 18 U.S.C. § 371 and Counts Two through Eight charged the respective

defendants with substantive counts of illegally making offers and payments of remuneration to physicians, in violation of 42 U.S.C. § 1320a-7b(b)(2)(A). Stewart and Bruens are charged in all 8 counts of the indictment. Vaughn is charged in Counts 1, 2 and 3; Sirockman is charged in Counts 1, 4 and 5.

2. Statement of Facts

The indictment in this case alleges the following facts:

In March, 1999, each of the defendants was a high-level employee of Serono Laboratories, Inc. ("Serono"), a biotechnology and pharmaceutical company based in Norwell, Massachusetts. Bruens was the Vice-President of Marketing and Stewart was the Vice-President of Sales in a business unit known as Metabolic and Immune Therapy ("M&IT"). Vaughn and Sirockman were Regional Directors - Vaughn was in charge of the Southeast Region and Sirockman was in charge of the Northeast Region.

M&IT was responsible for marketing and selling the drug Serostim, a drug that in August of 1996 received accelerated approval from the U.S. Food and Drug Administration ("FDA") only to treat a condition known as AIDS wasting. By February, 1999, Bruens, Stewart and other executives were aware that sales of Serostim were falling significantly short of their sales goals. In order to rectify the situation, Bruens, Stewart and others called an emergency meeting at the Boston Harbor Hotel for March 1, 1999, and summoned Defendants Sirockman, Vaughn and other

Regional Directors to attend. During the meeting, Bruens and Stewart informed the Regional Directors that they needed to "dig their way out" of the fiscal crisis, and proposed a program by which Serostim would reach a sales goal of "\$6 million in 6 days."

As part of the plan to achieve this sales goal, the defendants, and others, implemented a plan in which they asked certain doctors to write up to 30 prescriptions of Serostim in exchange for an all-expense paid trip to Cannes, France (paid for by Serono) to attend the 3rd Annual Conference on Nutrition and HIV Infection ("the Cannes Conference"). Defendants Vaughn and Sirockman, as Regional Directors, made the offer to individual doctors in their region to write the prescriptions in return for the trip to Cannes, or caused their sales representatives to extend the offer. Bruens and Stewart required the Regional Directors to report back to them on a daily basis as to the number of prescriptions obtained from the targeted doctors, among others. As part of the conspiracy, the Defendants caused Serono to pay for the travel expenses of the physicians and their guest(s) who actually attended the Cannes Conference.

ARGUMENT

**THE PARAGRAPHS IN THE INDICTMENT ARE NOT SURPLUSAGE
BECAUSE THEY ARE EVIDENCE OF ELEMENTS OF THE CHARGED CRIMES
AND PROVIDE USEFUL AND NECESSARY BACKGROUND INFORMATION**

The defendants seek to strike parts of the indictment as surplusage.¹ The sentence in paragraph 8 of the indictment which the defendants seek to strike, as well as paragraphs 9 and 10, explain the nature of the drug, Serostim, which was the subject of the charged kickbacks, the indications for which the drug was approved by the U.S. Food and Drug Administration ("FDA"), the manner in which Serostim was to be injected, its recommended dosage and its cost. Paragraph 11 describes the drugs that came onto the AIDS market at or around the same time as Serostim. These drugs treated the AIDS virus itself and their availability caused the bottom to drop out of the market for Serostim immediately following its launch. Finally, the defendants seek to strike one phrase in Paragraph 21 which describes one of the topics discussed at the Cannes conference.

Rule 7(d) of the Federal Rules of Criminal Procedure provides that "[u]pon the defendant's motion the court may strike surplusage from the indictment or information." Fed.R.Crim.P. 7(d). Courts interpreting Rule 7(d) have determined that its

¹. The defendants seek to strike a portion of ¶¶ 8 and 21 and ¶¶ 9, 10 and 11 in their entirety

standard is "rather exacting" and have recognized that only rarely is alleged surplusage stricken. United States v. Gambale, 610 F.Supp. 1515, 1543 (D.Mass. 1985); See also, United States v. El-Silimy, M.D., 228 F.R.D. 52, 58 (D.Me. 2005); United States v. Cisneros, 26 F.Supp.2d 24, 54 (D.D.C. 1998); United States v. Sawyer, 878 F.Supp. 279, 294 (D. Mass. 1995). "Language in the indictment which is information the government, in good faith, intends to properly prove at trial cannot be stricken as surplusage, no matter how prejudicial it may be." United States v. El-Silimy, 228 F.R.D. at 59, *citing*, United States v. Hill, 799 F.Supp. 86, 88-89 (D.Kan. 1992), United States v. Ianniello, 621 F.Supp. 1455, 1479 (S.D.N.Y. 1985); and, United States v. Lavin, 504 F.Supp. 1356, 1362 (N.D. Ill. 1981).

Indeed, allegations that concern essential elements of the crime or that provide "useful and important background information" should not be stricken. United States v. Cisneros, 26 F.Supp.2d at 55. As the Cisneros court explained, a "background section of an indictment is essential because it provides the defendant and the jury with the factual bases surrounding the charges against the defendant." Id., *citing*, United States v. Watt, 911 F.Supp. 538, 553 (1995).

The government contends that the allegations that the defendants seek to strike concern essential elements of the crime that are highly relevant to this case, and include important and

essential background. These allegations are not prejudicial.² Paragraphs 8 through 10 contain important information on Serostim which are key components to several essential elements of the crimes charged and upon which the entire case revolves. The jury cannot, and should not, be expected to decide a case in a vacuum without this information. It is imperative that the jury understands the drug's purpose and the condition for which it was approved by the FDA. The jury needs to be cognizant of the manner in which patients took the drug, the expense to the patients and the state Medicaid agencies, so that they can put the entire case in context.

More importantly, these paragraphs do not merely provide background information, but rather describe the nature and extent of the fraud, as well as motive and intent. The government expects that the evidence at trial will show that by March, 1999, the company, Serono Laboratories, Inc., and its top management, including the defendants, had reached a state of panic because sales of Serostim were far below its sales forecasts. The evidence described in paragraph 11 about the entry into the market place of protease inhibitors explains the reason for the decline in AIDS wasting, the only indication for which Serostim was approved by the FDA. As a result, from the moment Serostim

²Indeed, because of the relevance of the allegations, they should not be stricken even if they were highly prejudicial.

received accelerated approval from the FDA, its market began disappearing. This was a prime reason for the sales crisis that motivated the defendants to design, offer and pay the Cannes kickbacks. This evidence is key to showing the purpose of the conspiracy and motive. The other evidence, such as the cost of the drug to the Medicaid agencies and the course of treatment, are both elements of the crime and are likewise relevant to motive. All of this evidence provides the reasons why the doctors were reluctant to prescribe the drug, without the extra incentive or inducement, which included offering a kickback to key doctors.

In addition, the cost of prescriptions is directly relevant to show that payment was made by a federal healthcare program, the state Medicaid agencies. The cost of the drug is key to showing the "return on investment" ("ROI") to the company, i.e., the cost of the kickback per doctor (approximately \$10,000) in relation to the cost of the prescriptions sold (30 prescriptions @ \$12,000) yields an ROI of \$630,000. This rather large return on investment provides evidence of the defendants' motive, among other things. In addition, this information is also relevant for sentencing purposes. In order to determine the amount of fraud, the cost of the drug is an essential element. The government has given notice of this evidence to the defendants when it disclosed the testimony of one of the FDA reviewers of Serostim, Dr. Saul

Molozowski.³

Finally, the defendants themselves acknowledge that the allegations they seek to strike are at the very least background information. They argue that they should nonetheless be stricken because they will "open the door" to other background evidence that may imply "there is misconduct apart from what the Defendants have been charged with," in other words, R.404(b) evidence. In essence, the defendants' true motive for this motion is to get a blanket order ruling that all Rule 404(b) evidence is inadmissible.⁴ This clearly is an improper request, and, even if proper, this motion is clearly an improper means to obtain such a ruling.

In conclusion, the allegations which the defendants seek to strike from the indictment are highly relevant to this proceeding. They not only describe the background of the case, but are also components of several essential elements of the crime charged, as they prove the defendants' motivation for offering doctors a free trip to Cannes, France, in exchange for

³Of course, to the extent that this information is relevant for sentencing, the government need not prove these facts beyond a reasonable doubt at trial, but can prove them to the court by a preponderance of the evidence.

⁴The defendants previously attempted to do this via another tact - they filed a motion before U.S. Magistrate Judge Bowler for early disclosure of Rule 404(b) evidence. (Docket Nos. 36 and 37). This motion was denied, but nonetheless the government agreed to disclose its 404(b) evidence 30 days prior to trial.

prescribing Serostim.

CONCLUSION

Based upon the foregoing, the defendants' motion to strike surplusage from the indictment should be denied.

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United States Attorney

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Assistant U.S. Attorneys

CERTIFICATE OF SERVICE

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: 10/17/2006

/s/ Susan M. Poswistilo
SUSAN M. POSWISTILO
Assistant United States Attorney